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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,840	12/31/2001	Xiang-Jin Meng	AM100389	5348

7590 01/15/2003

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EXAMINER

WORTMAN, DONNA C

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,840

Applicant(s)

MENG ET AL.

Examiner

Donna C. Wortman, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 6, and 8-13, insofar as drawn to an isolated avian hepatitis E virus, immunogenic composition or vaccine comprising the virus, and method of immunizing using the virus, classified in class 424, subclass 93.6, e.g. Although claim 6 is rather confusing, for the purpose of this restriction, claim 6 has been interpreted as drawn to a virus.
- II. Claim 3, insofar as drawn to an avian hepatitis E virus genomic length polynucleotide, classified in class 536, subclass 23.72.
- III. Claim 3, insofar as drawn to a polynucleotide encoding an avian hepatitis E ORF1 protein, classified in class 536, subclass 23.72.
- IV. Claim 3, insofar as drawn to a polynucleotide encoding an avian hepatitis E RdRp protein, classified in class 536, subclass 23.72.
- V. Claim 3, insofar as drawn to a polynucleotide encoding an avian hepatitis E ORF2 protein, classified in class 536, subclass 23.72.
- VI. Claim 3, insofar as drawn to a polynucleotide encoding an avian hepatitis E ORF3 protein, classified in class 536, subclass 23.72.
- VII. Claims 4, 8, and 10-13 insofar as drawn to an isolated protein encoded by avian hepatitis E ORF1, vaccine, and method of immunizing, classified in class 424, subclass 225.1, e.g.
- VIII. Claims 4, 8, and 10-13, insofar as drawn to an isolated protein encoded by an avian hepatitis E RdRp gene, vaccine, and method of immunizing, classified in class 424, subclass 225.1, e.g.

- IX. Claims 4, 5, 8, and 10-13, insofar as drawn to an isolated protein encoded by an avian hepatitis E ORF2, vaccine, and method of immunizing, classified in class 424, subclass 225.1, e.g.
- X. Claims 4, 5, 8, and 10-13, insofar as drawn to an isolated protein encoded by an avian hepatitis E ORF3, vaccine, and method of immunizing, classified in class 424, subclass 225.1, e.g.
- XI. Claims 7, 17 and 18, drawn to an antibody and an immunoassay, classified in class 435, subclass 5, e.g.
- XII. Claims 8 and 10-13, insofar as drawn to a vaccine comprising an antigenic subunit and method of immunizing, classified in class 424, subclass 225.1, e.g.
- XIII. Claims 14-16, drawn to a method of propagating, inactivating or attenuating a virus by passaging, classified in class 435, subclass 237.
- XIV. Claims 19 and 20, drawn to a method of detecting involving nucleic acids, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

The products of Groups I-XII are distinctly different products that have different biological and immunological properties and/or different nucleotide and amino acid sequences.

The methods of Groups I and VII-XIV are distinctly different methods, requiring different process steps and/or different reagents and/or having different goals and outcomes.

Inventions XIII and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case virus can be isolated from natural sources or attenuated virus can be isolated after site-directed mutagenesis, e.g.

Inventions XIV and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used to specify the recombinant production of viral proteins.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and/or because the search required for any one group is not coextensive with the search required for any of the other groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
January 14, 2003